



Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV

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What's New in the Guidelines? (Last updated December 18, 2019; last reviewed December 18, 2019)

Antiretroviral Therapy to Prevent Sexual Transmission of HIV (Treatment as Prevention)

Clinical trials have shown that using effective antiretroviral therapy (ART) to consistently suppress plasma HIV RNA levels to <200 copies/mL prevents transmission of HIV to sexual partners. When ART is used to prevent HIV transmission, this strategy is called treatment as prevention (TasP), commonly known as Undetectable = Untransmittable or U=U.

The Panel on Antiretroviral Guidelines for Adults and Adolescents (the Panel) has added a new section to help providers integrate TasP into their clinical practice. The key recommendations include:

- Providers should inform persons with HIV that maintaining HIV RNA levels <200 copies/mL with ART prevents HIV transmission to sexual partners **(AII)**.
- Persons starting ART should use another form of prevention with sexual partners for at least the first 6 months of treatment and until an HIV RNA level of <200 copies/mL has been documented **(AII)**. Many experts recommend confirming sustained suppression before assuming that there is no risk of sexual HIV transmission **(AIII)**.
- Persons with HIV who rely on ART for prevention need to maintain high levels of ART adherence **(AIII)**. They should be informed that transmission is possible during periods of poor adherence or treatment interruption **(AIII)**.
- Providers should inform patients that maintaining an HIV RNA level of <200 copies/mL does not prevent acquisition or transmission of other sexually transmitted infections **(AII)**.

Dolutegravir Recommendations for Individuals of Childbearing Potential

The latest data on neural tube defects (NTDs) in infants born to women who received dolutegravir (DTG) around the time of conception have shown that the prevalence of NTDs is lower than initially reported (the rate has been reduced from 0.9% to 0.3%). However, this rate is still higher than the rate reported for infants born to individuals who received ART that did not contain DTG (0.1%).

In the previous version of the guidelines, the Panel did not recommend the use of DTG in persons who are pregnant and within 12 weeks post-conception or persons of childbearing potential who are planning to become pregnant or who are sexually active and not using effective contraception. Based on the new data, the Panel has revised these recommendations:

- Providers should discuss the benefits of using DTG and the risk of NTDs with the person of childbearing potential, to allow the person to make informed decisions about care.
- DTG may be used as an alternative antiretroviral (ARV) drug for individuals who are of childbearing potential and trying to conceive **(BII)** and those who are sexually active and not using contraception **(BII)**.
- For individuals who are using effective contraception, DTG may be used as a recommended option **(AII)**.
- Providers should refer to the [Perinatal Guidelines](#) for recommendations on the use of DTG during pregnancy.

More detailed recommendations on the use of DTG and other integrase strand transfer inhibitors (INSTIs) in persons of childbearing potential can be found in [Table 6b](#), as well as in different sections of the guidelines where DTG is discussed.

Laboratory Testing for Initial Assessment and Monitoring of People with HIV Receiving Antiretroviral Therapy

The Panel previously recommended monitoring fasting lipid profile and fasting glucose before and after initiation of ART. The new recommendation allows for random (nonfasting) tests, in accordance with recommendations from the recently published blood cholesterol and diabetes management guidelines.

Initiation of Antiretroviral Therapy

The Panel emphasizes the importance of screening and early diagnosis of HIV. In order for persons with HIV to benefit from early diagnosis, the Panel recommends that ART be started immediately or as soon as possible after diagnosis to increase the uptake of ART, decrease the time required to achieve linkage to care and virologic suppression for individual patients, reduce the risk of HIV transmission, and improve the rate of virologic suppression among persons with HIV (**AII**).

What to Start

Based on the results of two large, randomized controlled trials that showed that a two-drug regimen of DTG plus lamivudine (DTG/3TC) was noninferior to DTG plus tenofovir disoproxil fumarate (TDF)/emtricitabine (FTC), the Panel has added DTG/3TC to the list of *Recommended Initial Regimens for Most People with HIV*, **except for individuals**:

- With pre-treatment HIV RNA >500,000 copies/mL;
- Who are known to have active hepatitis B virus (HBV) coinfection; *or*
- Who will initiate ART before results of HIV genotype testing for reverse transcriptase or HBV testing are available.

Table 6b has been updated with revised recommendations on the use of DTG in individuals of childbearing potential.

Current data on the possible association between weight gain and the use of INSTIs and tenofovir alafenamide (TAF) are reviewed in the sections on INSTIs and nucleoside reverse transcriptase inhibitors.

Optimizing Antiretroviral Therapy in the Setting of Virologic Suppression

This section has been updated with new clinical trial data from switch studies that were published or presented since the last revision.

The Panel emphasizes the importance of reviewing a patient's ART history and recognizing any past instances of treatment failure and drug resistance when selecting a new ART regimen. The Panel also emphasizes that using two-drug ART regimens is not recommended for persons with active HBV coinfection.

Acute and Recent (Early) HIV Infection

This section has been updated to emphasize the importance of initiating ART as soon as possible after diagnosis of acute and recent HIV infection (**AII**).

Bictegravir/TAF/FTC has been added as a treatment option for persons with acute or recent HIV infection in cases where ART will be initiated before genotypic drug resistance testing results are available (**AIII**).

HIV and the Older Person

This section has been updated with new data related to older persons with HIV. These updates focus on:

- The need to identify individuals who are at risk of HIV and the need for early diagnosis;

- The impact of age on HIV disease progression and the increase in age-related comorbidities; *and*
- The importance of initiating ART while being aware of the complexities of management in older persons with HIV due to polypharmacy and the potential for drug-drug interactions.

The Panel emphasizes the importance of recognizing and managing HIV-associated neurocognitive disorder (HAND), which may be associated with reduced ART adherence and poorer overall health outcomes. The Panel also recognizes that mental health disorders in older persons with HIV is a growing concern; screening for depression and management of depression are critical components of care for these patients.

Tuberculosis/HIV Coinfection

This section has been updated with newly published data on short-course regimens in the treatment of latent tuberculosis infection and new drug-drug interaction data for ARV drugs and rifampin and rifapentine.

Cost Considerations and Antiretroviral Therapy

Key updates to this section include:

- An overview of the individual and societal costs of HIV care in the United States.
- A new sub-section on cost sharing that describes how varying cost-containment practices may impact the out-of-pocket payments for patients with Medicaid, Medicare, and Ryan White (AIDS Drug Assistance Program) coverage. To help clinicians to better understand the different ART-related pricing systems in the United States, a new table entitled Table 19a. Insurance and Health Program Prescription Drug Pricing and Access was created.
- A revised discussion of ARV drug costs that highlights the increased cost of brand-name drugs and the impact that anticipated commercialization of additional generic-based regimens will have on the cost of ART.
- An updated discussion of the economic value of several HIV-specific laboratory tests.

Table Updates

The following tables have been updated using data that has become available since the last revision:

- Tables 17 and 18 in [Adverse Effects of Antiretroviral Agents](#)
- Drug-Drug Interactions Tables [21a-e](#), [22a](#), and [22b](#)
- Appendix B: Drug Characteristics Tables